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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kurt Heinz Bauer

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EXAMINER

ORWIG, KEVIN S

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

05/25/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/582,865	Applicant(s) BAUER ET AL.	
	Examiner Kevin S. Orwig	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/14/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-14 are currently pending. Claims 1-13 are the subject of this Office Action. This is the first Office Action on the merits of the claims. Non-elected claim 14 is withdrawn from consideration.

Election/Restrictions

Applicants' election of Group I (claims 1-13) in the reply filed on Mar. 3, 2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claim 14 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

In the response of Mar. 3, 2010, applicants elected the following species:

Liquefied gas: dimethyl ether

Binding Agent: methacrylic acid acrylate copolymer (i.e. Eudragit)

Information Disclosure Statement

The references provided on the information disclosure statement(s) were considered and have been made of record to the extent that each was provided.

Specification (Title)

The title of the invention is not adequately descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. First, the claims are drawn to a method of making fast dissolving tablets, not the tablets themselves. Second, the current title does not adequately describe the process to which the claims under consideration are drawn. A revised title should be provided that describes the most significant features of the claimed process. At a minimum, this should include the use of pressurized liquefied gas.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by CLARKE (WO 03/057197; Published Jul. 17, 2003).

1. Clarke discloses a process for producing flash-dissolve and gastro-retentive tablets (title; abstract). The method involves injection molding a mixture of an active agent and polymer, under pressure, in the presence of a gas or supercritical fluid (abstract; p. 6, line 25 to p. 7, line 9; p. 7, line 29 to p. 9, line 2). Clarke teaches that any gas or supercritical fluid can be used, as long as it is compatible with the polymer component (p. 17, lines 23-26). Nitrogen and carbon dioxide are taught as preferred supercritical fluids (p. 16, lines 3-5; p. 18, lines 26-32). The critical temperature and

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pressure of supercritical CO₂ are 31.1 °C and 73 atm, respectively. Thus, Clarke reads on claims 1 and 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 6, 7, and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over GREEN (U.S. 5,976,577; Issued Nov. 2, 1999; Ref. AA on IDS dated 6/14/06) in view of VALDER (WO 02/41874; Published May 30, 2002).

2. Green discloses a process for preparing rapidly disintegrating oral dosage forms (title; abstract). The process involves contacting particulate or powdered (i.e. pulverized) active agents with a carrier in a solvent to form a suspension, forming discrete units by molding the suspension, and removing the continuous phase (i.e. solvent) (col. 2, lines 58-67; col. 5, lines 53-56; col. 6, lines 44-46 and 53-65; claims 1 and 21). Removal of the continuous phase solvent is preferably by freeze-drying or other methods involving reduced-pressure solvent removal (col. 7, lines 34-67; Examples 1 and 2; claim 16). Green does not teach the use of liquefied gasses.

3. However, Valder discloses a process suitable for the production of tablets, the process involving the use of liquefied gasses, which are liquefied at a pressure of 5-10 bar (abstract; p. 2, lines 22-33; p. 3, lines 11-22; p. 8, lines 10-14; p. 10, lines 14-19). Valder teaches the use of halogenated hydrocarbons including CFCs (p. 4, lines 22-30), and teaches that mixtures of such gasses may be used to achieve a convenient boiling point. Low boiling compounds may also be used (p. 3, lines 24-28). Valder teaches that the mixtures used preferably form azeotropes so that the mixture may be removed at a constant temperature without fractionation (p. 3, lines 28-30; p. 6, line 32 to p. 7, line 2). It is an object of Valder to provide an improved granulation process that solves the problems of prior art processes, such as the requirement for large amounts of

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energy and the long time periods to remove water from the composition (p. 2, lines 5-14).

4. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use liquefied gasses as the solvent in Green's method. One would have been motivated to do so since Green's preferable continuous phase is water (col. 5, lines 53-56) and since Valder provides an alternative method that overcomes the known problems with water removal from such compositions. Doing so amounts to no more than combining prior art elements according to known methods to yield predictable results, namely a process for producing fast-disintegrating tablets which overcomes the disadvantages of using water as a solvent. The combination of Green and Valder renders claims 1, 2, 4, 6, 7, 11, and 13 obvious.

5. Regarding claims 9 and 10, Valder teaches that the particles of active ingredient can be made much more robust by the introduction of dissolved material, by dissolving material into the liquid prior to use (p. 1, line 31 to p. 2, line 1). Valder teaches that the dissolved material can be a binder (which are taught to be preferable), including polymers such as enteric coating polymers like Eudragit (p. 2, lines 2-4; p. 5, lines 11-13). Preferred binders include methacrylate copolymers including those sold under the trade name Eudragit (i.e. elected species) (p. 5, lines 21-26; p. 7, lines), which may be dissolved in the hydrocarbon solvent, which is then mixed with the pharmaceutical substance (p. 6, lines 8-10). Thus, claims 9 and 10 are rendered obvious by Green and Valder.

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6. Regarding claim 12, Green teaches filler materials such as cellulose and mannitol (col. 3, lines 50-60), and Valder teaches the use of fillers such as mannitol along with the binder (p. 12, example). Thus, claim 12 is rendered obvious by Green and Valder.

Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green and Valder as applied to claims 1, 2, 4, 6, 7, and 9-13 above, and further in view of UNEP (UNEP booklet "Protecting the Ozone Layer (2001) Vol. 5. pp. 1-36).

7. The teachings of Green and Valder are presented *supra*. The references do not teach applicants' elected species of dimethyl ether DME. However, the use of DME would have been obvious to a skilled artisan because DME is a well-known substitute for hydrocarbons and CFCs, such as those used by Valder.

8. For example, UNEP teaches that DME is used extensively as a propellant, has excellent solvency and compatibility with water (p. 20, under section "Substitutes for propellants). UNEP teaches that DME has been used to produce low VOC formulations, which replace organic solvents (p. 20, under section "Substitutes for propellants). UNEP further teaches that it is possible to replace ozone-depleting solvents with a mixture of DME and water (p. 21, under section "Substitutes for solvents).

9. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute DME (i.e. elected species) for any of the halogenated hydrocarbons of Valder. One would have been

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motivated to do so since DME is a known replacement for hydrocarbons and ozone-depleting CFCs, such as are used by Valder. The combination of Green, Valder, and UNEP renders claims 3 and 5 obvious.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Green, Valder, and UNEP as applied to claims 3 and 5 above, and further in view of Clarke.

10. The teachings of Green, Valder, UNEP, and Clarke are presented *supra*. Valder does not teach the use of carbon dioxide in addition to the other liquefied gasses taught. However, the use of carbon dioxide would have been obvious to a skilled artisan because based on the teachings of Clarke.

11. As discussed above, Clarke teaches a method of producing fast-dissolving tablets substantially similar to that instantly claimed, and closely related to the method of Valder. Clarke teaches the use of chlorofluorocarbons, hydrofluorocarbons, aliphatic hydrocarbons, and carbon dioxide as well as the preferred use of pressurized carbon dioxide (p. 16, lines 3-5; p. 18, lines 11-14 and 26-32). Thus, Clarke establishes the functional equivalence of these gasses, and any artisan would recognize the utility of carbon dioxide in Valder's method. It is noted that the MPEP states that the selection of known materials based on their suitability for their intended uses is *prima facie* obvious. See MPEP § 2144.07.

Regarding the obviousness rejections herein, it is noted that a reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in

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the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

Claims 1-13 are rejected. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin S Orwig/

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611